

JUL 21 2005

**510(k)  
Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

K051215

**CELL-DYN Sapphire™ System**

**Submitted by**

Abbott Laboratories  
5440 Patrick Henry Drive  
Santa Clara, CA 95054

**Contact Person**

Michelle Roeding  
Phone (408) 567-3781      Fax (408) 982-4863

**Date Prepared**

May 10, 2005

**Proprietary Name**

CELL-DYN Sapphire™ System

**Common Name**

Automated Hematology Analyzer

**Classification Name**

Automated Differential Cell Counter  
(21 CFR 864.5220)

**Predicate Device**

Abbott CELL-DYN 4000 System

**Device  
Description**

The CELL-DYN Sapphire System is a benchtop analyzer consisting of the main analyzer with data station, flat panel display, printer, and associated reagents. The data station, display, and printer are stand-alone modules. The system has the capability to sample either from closed collection tubes via the autoloader, or from open collection tubes through the aspiration probe in the Open Tube mode.

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**Intended Use**

The CELL-DYN Sapphire System is a multiparameter, automated hematology analyzer designed for *in vitro* diagnostic use in clinical laboratories.

The CELL-DYN Sapphire System has the same intended use as previously cleared for the CELL-DYN 4000 System (predicate device).

**Similarities  
And  
Differences**

The CELL-DYN Sapphire System and the CELL-DYN 4000 System are similar in that:

- a) Both systems provide quantitation of the hemogram and automated WBC differential parameters in EDTA-anticoagulated human whole blood specimens.
- b) Both systems will accept specimens presented automatically by the autoloader or manually presented by the operator.
- c) Both systems utilize multiple measurement methodologies: impedance, laser optical scatter, fluorescence, and optical absorbance methods.
- d) Both systems measure RBC and PLT by laser optical scatter and focused-flow impedance with injection metering.
- e) Both systems measure WBC by laser optical scatter and fluorescence.
- f) Both systems use fluorescence to enumerate reticulocytes, NRBC, CD61, and CD3/4/8.
- g) Both systems provide Dispersional Data Alerts, Suspect Parameter Messages, and Suspect Population Flags to assist in data review.
- h) Both systems accept input from keyboard and send data output to: video screen, hard drive, and printer; and both systems provide RS232 Interface to an on-line LIS as well as using microprocessors for systems control, data acquisition, and data analysis.

The CELL-DYN Sapphire System and the CELL-DYN 4000 System are different in that:

- a) The CELL-DYN Sapphire System uses a solid state laser to facilitate both optical scatter and fluorescence measurements, while the CELL-DYN 4000 uses an Argon-ion laser.

- b) The CELL-DYN Sapphire System uses a Unix based Linux operating system, while the CELL-DYN 4000 uses a Unix based Lynx operating system.
- c) The CELL-DYN Sapphire System has the ability to download raw list mode data (FCS type) to media for analysis, while the CELL-DYN 4000 System does not have this capability.
- d) The CELL-DYN Sapphire System has internal pneumatic components, while the CELL-DYN 4000 has a separate external pneumatic unit.

**Medical - Clinical  
Study Protocol**

The Medical - Clinical Study Protocols for the CELL-DYN Sapphire are found in Attachment E.

**Equivalency  
Data Summary**

The CELL-DYN Sapphire System is a multiparameter, automated hematology analyzer designed for *in vitro* diagnostic use in clinical laboratories. The CELL-DYN Sapphire System, which includes reagents and software, was compared in clinical trials to the CELL-DYN 4000 System. The data compiled supports the claim that the CELL-DYN Sapphire System is substantially equivalent to the CELL-DYN 4000 System and includes data for background, carryover, comparability (correlation), imprecision (reproducibility), analytical measurement range (linearity), and sensitivity and specificity. The data supporting the claim that the CELL-DYN Sapphire is substantially equivalent to the CELL-DYN 4000 is found in Attachment G.

**Conclusion**

The CELL-DYN Sapphire System is substantially equivalent to the CELL-DYN 4000 (predicate device). The differences noted do not pose new questions of safety and effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Michelle Roeding  
Section Manager, Regulatory Affairs  
Abbott Laboratories  
Hematology Business Unit  
5440 Patrick Henry Drive  
Santa Clara, CA 95054

JUL 21 2005

Re: k051215  
Trade/Device Name: CELL- DYN Sapphire™ System  
Regulation Number: 21 CFR 864.5220  
Regulation Name: Automated differential cell counter  
Regulatory Class: Class II  
Product Code: GKZ  
Dated: May 10, 2004  
Received: May 12, 2004

Dear Ms. Roeding:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

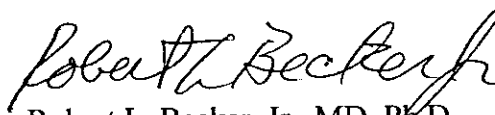
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert L. Becker, Jr.", written in a cursive style.

Robert L. Becker, Jr., MD, Ph.D

Director

Division of Immunology and Hematology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

### Indications for Use Statement

510(k) Number (if known): K 051215

Device Name: CELL-DYN Sapphire™ System

Indications for Use:

The CELL-DYN Sapphire System is a multiparameter, automated hematology analyzer designed to provide complete blood count with WBC Differential, NRBC, Reticulocyte and Immature Reticulocyte Fraction enumeration, and CD61 and CD3/4/8 immunofluorescent analysis on EDTA-anticoagulated whole blood.

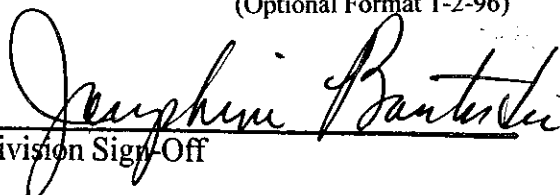
(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K051215

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